Cardiac Science Powerheart, CardioVive, CardioLife; GE Responder and Responder Pro; and Nihon-Kohden Automated External Defibrillators (AEDs): Class I Recall - Defective Compo...

U.S. Food & Drug Administration

- Powerheart 9300A, 9300E, 9300P, 9390A, and 9390E
- CardioVive 92532, 92533
- CardioLife 9200G and 9231
- GE Responder and Responder Pro
- Nihon-Kohden AEDs

AUDIENCE: Emergency Medicine, Cardiology, Risk Manager

ISSUE: FDA notified healthcare professionals and medical care organizations of the Class 1 recall of the listed AEDs which contain a component that may fail unexpectedly due to a defect. If the component were to fail during a rescue attempt, the AED may not deliver defibrillation therapy, causing serious adverse health consequences, including death. The unit's self test may not detect the failure or impending failure of the component.

BACKGROUND: These products are used for emergency treatment of victims showing symptoms of sudden cardiac arrest who are unresponsive and not breathing. These AEDs were manufactured and distributed from July 1, 2011 through December 30, 2011.

RECOMMENDATION: Affected customers are advised to contact the firm to arrange for delivery of shipping materials for an immediate return of their AEDs for repair. The affected devices will receive a hardware correction, and the same serial number device will be returned to the customer in most cases.

[03/02/2012 - Recall Notice [1] - FDA]
[01/13/2012 - Urgent Voluntary Medical Device Recall Letter [2] [3]- Cardiac Science]

SOURCE [4]

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http://www.mdtmag.com/news/2012/03/cardiac-science-powerheart-cardiovive-cardiolife-ge-responder-and-responder-pro-and-nihon-kohden-automated-external-defibrillators-aeds-class-i-recall-defective-compo?qt-most_popular=0

Links:
[1] http://www.fda.gov/MedicalDevices/Safety/RecallsCorrectionsRemovals/ListofRecalls/ucm294452.htm
[2] http://www.cardiacscience.com/assets/023/7751.pdf
[3] http://www.fda.gov/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm
[4] http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm294538.htm